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ORIGINAL ARTICLE

Use of a risk assessment method to improve the safety of negative pressure wound therapy

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Abstract

To conduct a risk analysis of the negative pressure wound therapy (NPWT) care process and to improve the safety of NPWT, a working group of nurses, hospital pharmacists, physicians and hospital managers performed a risk analysis for the process of NPWT care. The failure modes, effects and criticality analysis (FMECA) method was used for this analysis. Failure modes and their consequences were defined and classified as a function of their criticality to identify priority actions for improvement. By contrast to classical FMECA, the criticality index (CI) of each consequence was calculated by multiplying occurrence, severity and detection scores. We identified 13 failure modes, leading to 20 different consequences. The CI of consequences was initially 712, falling to 357 after corrective measures were implemented. The major improvements proposed included the establishment of 6-monthly training cycles for nurses, physicians and surgeons and the introduction of computerised prescription for NPWT. The FMECA method also made it possible to prioritise actions as a function of the criticality ranking of consequences and was easily understood and used by the working group. This study is, to our knowledge, the first to use the FMECA method to improve the safety of NPWT.

Introduction

Negative pressure wound therapy (NPWT) is widely used to treat acute and chronic wounds, such as pressure ulcers, lower leg wounds, diabetic foot ulcers, surgical incision, traumatic wounds and burns (1,2). It is based on the application of a uniform negative pressure (i.e. a pressure below that of the ambient atmosphere), leading to the removal of wound exudates, an increase in local blood flow and the stimulation of granulation tissue formation (3). NPWT devices consist of an interface material that is placed on the wound and covered with an adhesive semi-occlusive dressing. Polyurethane foam is the most widely used interface material, but other interface materials, such as polyvinyl alcohol sponges and gauzes, can be used (4,5). Wound exudates are evacuated via a system of tubing placed on top of the dressing and connected to a collection canister and a vacuum source.

Despite the numerous NPWT guidelines published both by the European Wound Management Association and the manufacturers of NPWT devices, the necessary precautions

Key Messages

- despite the numerous guidelines, the necessary precautions are not always taken with the NPWT medical devices
- serious complications have been reported with NPWT such as bleeding, infections from the original open wounds or from retention of pieces of dressing in the wound, skin irritation and pain
- the FMECA method has already been used successfully, for various purposes, in hospitals
- the aim of the study was to conduct a risk analysis of the NPWT care process and to improve the safety of NPWT at our hospital
- 13 failure modes leading to 20 different consequences were identified
- the criticality index of consequences was initially 712, falling to 357 after corrective measures were implemented

- the major improvements proposed included the establishment of six-monthly training cycles for nurses, physicians and surgeons and the introduction of computerized prescription for NPWT
- the NPWT procedure entails a number of risks that can be reduced by simple measures
- the FMECA method was useful for prioritizing actions according to their criticality ranking
- an important feature of the study was the adaptation of the risk assessment method to score consequences rather than failure modes
- the subjectivity is one of the major limitations of the FMECA method and the method is not designed to deal with multiple-failure scenarios
- in conclusion, we were able to identify most of the failure modes of the NPWT care process by using the FMECA method and we intend to extend this work to ambulatory care in the future

are not always taken with these medical devices (6–8). Moreover, serious complications of NPWT have been reported: bleeding, infections from the original open wounds or from retention of pieces of dressing in the wound, skin irritation and pain (9–11). In the past few years, the US Food and Drug Administration (FDA) has received several reports of deaths and severe injuries due to the use of NPWT systems. These reports led the FDA to issue recommendations concerning the use of NPWT, in November 2009 (12,13). Two months later, in the wake of similar reports in France, the French National Authority for Health (*Haute Autorité de Santé*) published recommendations for health professionals (14). These recommendations focused on the training of medical staff and the consideration of contraindications and patient-related risk factors.

At this time, a severe complication involving NPWT occurred at the European Georges Pompidou Hospital. A 61-year-old man with cardiomyopathy treated with oral anticoagulants was admitted to the Department of Internal Medicine for a fever of unknown origin. A few days later, he developed a pressure ulcer that the medical staff decided to treat by NPWT. Two days after the application of NPWT, the patient presented hypovolemic shock due to massive bleeding resulting from the rupture of a small artery caused by the suction involved in NPWT. The anticoagulant treatment and NPWT were stopped and the patient remained stable over the next 24 hours. The outcome was good.

This incident led to the establishment of a multidisciplinary group for its analysis and the establishment of preventive measures. In this particular case, the medical staff had not taken the risk factors sufficiently into account and the frequency of patient monitoring was inadequate. On the basis of FDA and French National Authority for Health recommendations, the multidisciplinary group developed guidelines for the use of NPWT adapted to our institution. These guidelines were then distributed and training sessions were held for nurses, surgeons and physicians.

The multidisciplinary group suggested that a more comprehensive approach, including risk assessment for the NPWT care process, should be implemented. The failure modes, effects and criticality analysis (FMECA) approach was selected for this risk assessment evaluation, because it highlights likely errors with relatively high probability and the severity of consequences. Moreover, FMECA has already been used successfully, for various purposes, in hospitals (15–17). It serves as a decision tool, enabling the medical team to determine whether a risk is acceptable or not, and it can be used to estimate the potential impact of various improvement measures. However, classical FMECA could not be used because of the nature of the NPWT care process. FMECA is designed to study industrial and production processes. Besides, using an adapted method close to classical FMECA seemed an interesting choice to conduct this study. To our knowledge, no specific risk analysis method for care processes has been validated. The aim of this study was to conduct a risk analysis of the NPWT care process and to improve the safety of NPWT at our hospital.

Methods

The multidisciplinary group set up a dedicated working group for this study. This working group consisted of two senior nurses (from the orthopaedic surgery and surgical intensive care units), one nurse, one nursing director, two hospital pharmacists responsible for the management of sterile medical devices, one intensive care physician and a moderator. The aim was to establish a group of professionals very familiar with NPWT. Each professional brought unique experience and skills to the team.

FMECA scrutinises a given process, identifying likely errors ('failure mode'), and estimating their probable effects, even before they take place. Unlike failure modes, effects analysis, FMECA includes a quantitative assessment of the criticality of each failure mode. The criticality index (CI) is calculated by multiplying three components – likelihood of occurrence, severity and capacity for detection – determined from reference scales based on known or estimated data for each failure mode. FMECA classifies the failure modes and identifies the leading critical events. The aim is to determine whether each of the risks identified is acceptable. If a risk is considered unacceptable, corrective measures must be taken to decrease the CI and improve the safety of the process. By contrast to classical FMECA, we decided to score consequences rather than the failure modes identified. This choice is justified because NPWT care cannot be defined as a product. We had to deal with a patient care process in which most failure modes generally are unidentifiable until they become consequences. Thus, we chose to quote consequences as they can be easily observed. On the other hand, to quote consequences is all the more relevant because they are precisely what we want to avoid happening. Following the identification of consequences, the working group tried to identify the most appropriate measures to be taken and to assess their potential impact on the safety of the process.

The analysis began with a description of the entire process and its dissection into major steps. Each of these major steps was described in detail. A brainstorming session was organised to consider possible ways in which the process could fail,

Table 1 FMECA of the occurrence, severity and ranking of consequences

	Probability	Ranking
Occurrence of the consequence (frequency)		
Remote (no known occurrence)	1/10 000	1
Low (possible but no known data)	1/5000	2
Moderate (documented, but not frequent)	1/200	3
High (documented and frequent)	1/20	4
Very high (documented, almost certain)	1/10	5
Gravity of the consequence (severity)		
Slight annoyance (may affect the system)	–	1
Moderate system problem (affects the system/may affect the patient)	–	2
Minor injury (e.g. re-dressing the wound, patient stress)	–	3
Major injury (e.g. local infection, pain)	–	4
Terminal injury (e.g. systemic infection, necrosis)	–	5
Capacity for detection of the consequence (detectability)		
Very high (system will always detect error before reaching patient)	9/10	1
High (high probability of detection before reaching patient)	7/10	2
Moderate (moderate probability of detection before reaching patient)	5/10	3
Low (low likelihood that failure will be detected before reaching patient)	2/10	4
Remote (detection impossible at any point within the system)	0/10	5

FMECA, failure modes, effects and criticality analysis.

for each step. The members of the working group were asked to address the following question: 'What could possibly go wrong?'. For each failure mode identified, the working group searched for possible causes and potential effects. To answer that question, the members of the group had to rely on their own experiences with NPWT. Most potential effects identified during the brainstorming were issued from that experience. To be more exhaustive, for the second time, we compared these possible consequences with the data relative to the complications with NPWT that had been reported to the FDA between January 2000 and February 2011. The consequences reported to the FDA were discussed and those which may occur in our NPWT care process were also taken into account. Then after, the working group scored the likelihood of occurrence (incidence) for each potential effect, the severity of would-be consequences and the likelihood of detection, on a scale of 1–5. Estimates were obtained by achieving a consensus within the working group. The scales used are reported in Table 1.

The CI of each identified consequence was calculated by multiplying the frequency, effect and likelihood of detection scores (CI: 1–125). The CIs were then ranked, in descending order, and analysed by the working group. For each CI obtained, actions were proposed for reducing the CI and improving the safety of the process. The working group also assessed the expected impact of these measures and evaluated the residual risk by calculating CIs (expected CIs). Finally, the change in CI was discussed and the acceptability of the residual risk evaluated. If the residual risk was not considered acceptable, further improvements were proposed and their effect on the CI determined.

Results

The working group carried out the analysis between May and July 2011, during six work meetings, each lasting about 2 hours.

Definition of the process and identification of failure modes

The NPWT process was split into four major steps: prescription, application of the dressing, monitoring and dressing removal. All major steps were divided into sub-steps (Table 2). We then identified 30 vulnerable points, which we grouped according to their consequences (those leading to the same consequences were grouped together). We identified 13 failure modes, leading to 20 different consequences, which we described in detail, together with their causes and potential effects (Table 2).

Criticality analysis

The CIs of consequences were calculated from the defined frequency, severity and likelihood of detection scores (Table 3).

The initial total CI was 712 and the total expected CI after the implementation of improvement measures was 357. The proposed measures would therefore be expected to decrease the total CI by 51%. Individual CIs were reduced by a mean factor of 2·2, with 20 consequences displaying a mean decrease in CI by a factor of at least two. No CI increased and only five CIs would be expected to remain unchanged.

Before the proposed improvements, the highest risks were those of bleeding (CI = 75), local infection (CI = 60), systemic infection (CI = 48) and cerebrospinal fluid (CSF) leakage (CI = 50). After the corrective measures, the highest expected CI were those of anatomical complications (expected CI = 32) and patient stress (expected CI = 30). The CI of bleeding was reduced by a factor of 4·7 (expected CI = 16).

Possible improvement measures

Each consequence was studied, taking into account the initial CI, the related failure mode and the associated potential causes. For each consequence, the working group sought to reduce the CI by modifying the severity of the outcome, its

Table 2 Description of the NPWT process and identified failure modes at the European Georges Pompidou Hospital

Step	Sub-step	Identified failure mode
Prescription	Wound assessment	Inadequate wound assessment (e.g. lack of wound assessment, incorrect appraisal of the wound)
	Eligibility check	Incorrect appraisal of the patient (e.g. comorbidity not taken into account)
	Prescription	Prescription errors (e.g. lack of prescription, inadequate prescription, lack of information)
Dressing application	Patient preparation	Lack of patient information
	Wound preparation	Inadequate connections (e.g. connection to the vacuum system of the hospital)
	Material preparation	Incorrect settings (e.g. incorrect intensity)
	Dressing application	Aseptic failure (e.g. poor compliance with aseptic techniques)
	Dressing connection	Failure of analgesia* (e.g. inadequate pain assessment, inadequate pain medication)
		Failure of suction
Monitoring	Material monitoring	Inadequate material monitoring
		Failure of analgesia*
	Clinical monitoring	Inadequate clinical monitoring (e.g. unscheduled monitoring, poor monitoring)
		Power failure (≥2 hours)
		Failure of suction
Dressing removal	Patient preparation	Failure of analgesia*
	Dressing disconnection	Difficulty in removing foam (e.g. adhesion of the dressing to the wound, retention of pieces of foam dressing in the wound)
	Dressing removal	

NPWT, negative pressure wound therapy.
*Failure of analgesia is the only non-specific failure mode.

Table 3 Comparison of criticality indices before and after improvement measures

Consequences of failure modes	Criticality index		Reduction factor (before/after)
	Before improvement measures	After improvement measures	
Bleeding	75	16	4·7
Systemic infections	60	20	3
CSF leakage	50	25	2
Local infections	48	24	2
Neurovascular damage	45	10	4·5
Patient stress	45	30	1·5
Necrosis	40	10	4
Inadequate care	40	8	5
Relative contraindication	36	16	2·3
Refusal of treatment	36	24	1·5
Pain	36	18	2
Poorly executed care	36	18	2
Wound complications	32	24	1·3
Anatomical complications	32	32	1
Absolute contraindication	30	20	1·5
Prolonged care	27	18	1·5
Loss of patient confidence	18	18	1
Delayed care	16	16	1
Redressing the wound	6	6	1
Canister leakage	4	4	1
Total	712	357	
Mean			2·2

CSF, cerebrospinal fluid.

frequency or the likelihood of its detection. The proposed improvement measures are listed in Table 4.

The working group proposed additive measures for improving safety before or during the process. The main improvements were based on the training of medical staff according to the NPWT guidelines, the introduction of an NPWT monitoring checklist and computerised prescription. NPWT involves a large number of tasks. The working group gave priority to strategies that decreased the need for memorisation. For example, the working group suggested that it should be possible for physicians to access to online assistance for all treatment items when prescribing NPWT: treatment duration, type of foam, generator settings, and so on. The prescription process should be associated with a checklist of monitoring issues, to help nurses. One particularly important measure is the systematic training of all professionals using NPWT, including both nurses and physicians. This measure should include a training cycle every 6 months, for all professionals who have recently arrived at our institution. Before the analysis, a survey conducted by the hospital pharmacy showed that only half the nurses using the device had been trained in its use. Most of the nurses had received only brief training from the manufacturer of the NPWT device. These measures would standardise the management of NPWT patients and improve communication between health professionals.

Table 4 Improvement measures proposed

Update of NPWT guidelines:
Precautions for wounds near the spine
Information about neurological monitoring
Training cycles every 6 months for nurses, physicians and surgeons
Computerised prescription with online assistance
Introduction of a monitoring checklist for NPWT
Additional generator for nights and weekends
Systematic use of 300 ml canisters (lowest volume available)
Introduction of a wound monitoring form
Development of a guide to NPWT for patients
Regular assessment of pain
Use of 50% nitrous oxide and 50% oxygen (MEOPA) conscious sedation for dressing application and removal

NPWT, negative pressure wound therapy.

The working group also proposed protective measures, including the systematic use of low-volume canisters. The generator alarm is activated when the collection canister is

full. Thus, to minimise the risk of massive bleeding, the working group has recommended the use of canisters with the lowest possible volume. Another measure making it possible to overcome dangerous practices would be the supply of an additional generator to hospital care units. Indeed, it is not currently possible to obtain generators during the night and at weekends. In the absence of such a generator, the health care professionals had adopted the practice of connecting the dressing to the vacuum system of the hospital, which has no alarm.

Discussion

NPWT may be considered a high-risk treatment for wounds. To our knowledge, this study is the first to apply the FMECA method to NPWT. Many authors have reported injuries related to the technique, but no risk analysis for NPWT has been published. We show here that the NPWT procedure entails a number of risks that can be reduced by simple measures and that a significant decrease in criticality, of more than 50%, can be expected following the adoption of these measures. However, the improvement measures proposed have only just been implemented and it is too early to determine their real effects. The next step will be to assess the efficacy of the proposed measures some time after implementation.

The FMECA method was useful for prioritising actions according to their criticality ranking. Guidelines had already been developed for the use of NPWT at our hospital, but this risk analysis highlighted some omissions. Indeed, some of the issues identified in this analysis had not previously been identified by the multidisciplinary group. This highlights the potential contribution of the FMECA method, over and above that of simple group discussion. The guidelines for NPWT at our hospital have been modified accordingly, with the incorporation of new measures.

Many of the improvement measures proposed here are directly applicable to other institutions. Some are based on common sense and are easy to implement. For instance, the use of low-volume canisters and the development of monitoring checklists are not specific to our organisation. Nevertheless, the development of our own guidelines for NPWT was highly labour-intensive and was adapted to our own context. These guidelines may therefore not be entirely appropriate for use, in their current state, at other hospitals. Moreover, some unusual consequences were identified and analysed. For example, CSF leakage due to NPWT has been reported only once, but this possibility led us to consider the possible neurological risks of the treatment. The working group therefore proposed the exploration of neurological function through the monitoring checklist.

An important feature of our analysis was the adaptation of FMECA to score consequences rather than failure modes. By contrast to production processes, most of the failure modes in a patient care process cannot be detected before they occur because the process involves the patient directly. Moreover, many potential errors can only be detected when they become consequences. For instance, inadequate asepsis during surgery cannot be detected directly, becoming apparent only through the infections that subsequently develop.

To facilitate the analysis, we chose to group consequences that are quite similar under generic terms. Indeed, the similar consequences often have comparable origins. For instance, we decided to gather the complications such as enterocutaneous fistula with intestinal fistula and various types of stenosis under the term of 'anatomical complication'. Whenever a consequence, such as CSF leakage, was too specific to be grouped, we chose to mention it directly even if it was a rare event.

The FMECA method is subject to several limitations. Among the major limitations, the subjectivity of the method has been largely described in the literature (16,18,19). When ranking the criticality indices of different consequences, members of the working group were sometimes influenced by events that had really occurred and it was difficult to take these events into account properly, without maximising or minimising them. Another limitation of this analysis is the large number of trivial cases considered, which was sometimes very time-consuming for minor issues. Indeed, the time-consuming aspect of the method has already been mentioned in previous works (15). However, we had already used other risk analysis methods, such as preliminary risk analysis and hazard analysis and critical control points, both of which were much more time-consuming than FMECA (20,21).

Moreover, although the method was readily understood and used by the group members, several problems associated with its practical implementation were identified. Notably, a difficult task was the establishment of a well-balanced FMECA working group. Initially, surgeons should have been involved in the working group, but they did not wish to participate. We can imagine that the same analysis performed by two different groups could have produced different results. For example, surgeons could have identified specific failure modes during the dressing application or ranked differently the criticality indices of consequences. To check the robustness of the method, a new and independent group could have performed the same analysis of both processes. However, the aim of the analysis was to identify the potential risks of the NPWT and to rapidly provide possible improvement measures. The verification of robustness would have been very time-consuming and there is no evidence that the results would have been significantly different with another group. In addition, the working group was large, multidisciplinary and included neutral investigators. According to the literature, the working group was well balanced to reduce judgement bias (16).

Furthermore, each consequence was considered individually and the effects of several combined consequences were not taken into account. FMECA is not designed to deal with multiple-failure scenarios. In clinical situations, this limitation of the method makes its use more complicated. Indeed, many clinical failures are closely related and the consequences are not always predictable. For example, tissue necrosis may lead to local or systemic infections of various severities. Another important factor that must be taken into account is that we chose to consider only direct consequences of identified failure modes. The working group did not consider the possibility of new consequences occurring after an initial consequence. For this reason, the death of the patient and limb amputation were

considered to be indirect outcomes and were not taken into account.

In conclusion, by using the FMECA method, we were able to identify most of the failure modes of the NPWT care process and to forecast their possible consequences. This method also facilitated the definition and implementation of improvement measures. Another study based on the same method will be required to assess the real impact of the implemented measures, to determine whether the expected results have been achieved. Further studies will facilitate the adjustment of the implemented measures, to improve the safety of the process. Finally, as most of the problems with NPWT reported to the US FDA occurred at home (10), we intend to extend this analysis to ambulatory care in the future.

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